ARTICLE 14. REGISTRATION OF NONIONIZING RADIATION SOURCES AND STANDARDS FOR PROTECTION AGAINST NONIONIZING RADIATION

R12-1-1401. Registration of Nonionizing Radiation Sources and Service Providers

A. A person shall not use a nonexempt nonionizing radiation source, unless the source is registered by the Agency.

B. A person who possesses a nonexempt nonionizing source shall submit to the Agency an application for registration at least 30 days before its first use.

1. A person who possesses a nonexempt source listed in R12-1-1302(F) shall register the source with the Agency.
2. A person applying for the registration of a nonexempt source shall use an application form provided by the Agency.
3. An applicant shall provide the information identified in Appendix B of this Article.

C. A registrant shall notify the Agency within 30 days of any change to the information contained in the registration, or sale of a source that results in termination of the activities conducted under the registration.

D. In addition to the application form, an applicant shall remit the applicable registration fee, specified in R12-1-1306.

E. A person who is operating more than one facility, where one or more nonexempt nonionizing sources are used, shall apply for a separate registration for each facility.

F. A person in the business of installing or servicing nonexempt nonionizing sources shall apply to the Agency for registration 30 days before furnishing the service. The person shall apply for registration on a form furnished by the Agency and shall provide the information required by A.R.S. § 30-672.01.

Historical Note

Adopted effective April 2, 1990 (Supp. 90-2). Repealed effective January 2, 1996 (Supp. 96-1). New Section made by final rulemaking at 11 A.A.R. 61, effective February 5, 2005 (04-4).

R12-1-1402. Definitions

General definitions:

"Controlled area" means any area to which human access is restricted for the purpose of protection from nonionizing radiation.

"Direct supervision" means that a licensed practitioner supervises the use of a source for medical purposes while the practitioner is present inside the facility where the source is being used.

"Indirect supervision" means: for lasers or IPL devices used for hair removal procedures, there is at a minimum, responsible supervision and control by a licensed practitioner who is easily accessible by telecommunication.

"Licensed practitioner" (See R12-1-102)

"Medical director" means a licensed practitioner, as defined in R12-1-102, who delegates a laser, IPL, or other light-emitting medical device procedure to a non-physician and is qualified to perform the procedure within the scope of practice of the license.

"Nonexempt nonionizing source" means any system or device that contains a nonionizing source listed in R12-1-1302(F).

"Operator" means a person who is trained in accordance with this Article and knowledgeable about the control and function of a nonionizing device regulated under this Article.

"Other cosmetic procedure" means a method of using medical lasers or intense pulse light (IPL) devices approved by the Federal Food and Drug Administration (FDA), for the cosmetic purpose of spider vein removal, skin rejuvenation, non-ablative skin resurfacing, skin resurfacing, port wine stain removal, epidermal pigmented skin lesion removal, or tattoo removal; and does not include hair removal.

Laser definitions:

"Accessible emission limit (AEL)" means the maximum accessible emission level of laser or collateral radiation permitted within a particular class.

"Accessible radiation" means laser or collateral radiation to which human access is possible.

"Angular subtense" means the apparent visual angle, a, as calculated from the source size and distance from the eye.

"Aperture" means an opening in the protective housing or other enclosure of a laser product, through which laser or collateral radiation is emitted, allowing human access to the radiation.

"Aperture stop" means an opening serving to limit the size and to define the shape of the area over which radiation is measured.

"Certified laser product" means that the product is certified by a manufacturer in accordance with the requirements of 21 CFR 1040.10, April 1, 2004, which is incorporated by reference, published by the Office of Federal Register National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. This incorporation by reference contains no future editions or amendments.

"CDRH" means the Center for Devices and Radiological Health.

"Classes of lasers" means the following categories of lasers, defined in 21 CFR 1040.10, April 1, 2004, which is incorporated by reference, published by the Office of Federal Register National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency: Class 1, Class 2, Class 2a, Class 3, Class 3a, Class 3b, and Class 4. This incorporation by reference contains no future editions or amendments.

"Collateral radiation" means any electronic product radiation, except laser radiation, emitted by a laser product as a result of operation of the laser or any component of the laser product that is physically necessary for operation of the laser. The accessible emission limits for collateral radiation are specified in 21 CFR 1040.10, April 1, 2004, which is incorporated by reference, published by the Office of Federal Register National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. This incorporation by reference contains no future editions or amendments.

"Continuous wave" (cw) means the output of a laser that is operated in a continuous rather than a pulsed mode. For purposes of this Article, a laser operating with a continuous output for a period ≥ 0.25 seconds, is regarded as a cw laser.

"Cosmetic procedure protocol" means a delegated written authorization to select specific laser or IPL settings, initiate a laser or IPL procedure, and conduct necessary follow-up procedures.

"Demonstration laser" means any laser manufactured, designed, intended, or used for purposes of demonstration, entertainment, advertising display, or artistic composition.

"Embedded laser" means an enclosed laser with an assigned class number higher than the inherent capability of the laser system in which it is incorporated, where the system's lower classification is due to engineering features that limit accessible emission.

"Enclosed laser" means a laser that is contained within its own protective housing or the protective housing of a laser or laser system in which it is incorporated. Opening or removing the protective housing provides more access to laser radiation above the applicable MPE than is possible with the protective housing in place. (An embedded laser is a type of enclosed laser.)

"Federal performance standards for light-emitting products" means the regulations in 21CFR 1040.10, April 1, 2004, which is incorporated by reference, published by the Office of Federal Register National Archives, and Records Administration, Washington, D.C. 20408, and on file with the Agency. This incorporation by reference contains no future editions or amendments.

"Human access" means the capacity to intercept laser or collateral radiation by any part of the human body.

"Incident" means an event or occurrence that results in actual or suspected accidental exposure to laser radiation that has caused or is likely to cause biological damage.

"Integrated radiance" means radiant energy per unit area of a radiating surface per unit solid angle of emission, expressed in joules per square centimeter per steradian.

"Irradiance" means the time-averaged radiant power incident on an element of a surface divided by the area of that element, expressed in watts per square centimeter.

"Laser" See the definition in Article 1.

"Laser energy source" means any device intended for use in conjunction with a laser to supply energy for the operation of the laser. General energy sources, such as electrical supply mains or batteries, are not considered laser energy sources by the Agency.

"Laser facility" means a facility where one or more lasers are used. For purposes of this definition a Class 1 facility is a facility that has one or more Class 1 lasers; a Class 2 facility is a facility that has one or more Class 2 or 2a lasers; a Class 3 facility is a facility that has one or more Class 3, 3a, or 3b lasers, and a Class 4 facility is a facility that has one or more Class 4 lasers. Facilities that contain more than one laser class are classified according to the highest laser class in use at the facility.

"Laser product" means any manufactured product or assemblage of components that constitutes, incorporates, or is intended to incorporate a laser or laser system. A laser or laser system that is intended for use as a component of an electronic product is itself considered a laser product.

"Laser protective device" means any device used to reduce or prevent exposure of personnel to laser radiation. This includes: protective eyewear, garments, engineering controls, and operational controls.

"Laser radiation" means all electromagnetic radiation emitted by a laser product, within the spectral range specified in the definition of "laser," which is produced as a result of controlled stimulated emission or that is detectable with radiation so produced through the appropriate aperture stop and within the appropriate solid angle of acceptance.

"Laser Safety Officer (LSO)" - means any individual, qualified by training and experience in the evaluation and control of laser hazards, who is designated by the registrant and has the authority and responsibility to establish and administer the laser radiation protection program for a particular class of facility.

"Laser system" means a laser in combination with an appropriate laser energy source with or without additional incorporated components.

"Limited exposure duration (Tmax)" means an exposure duration that is specifically limited by design or intended use.

"Maintenance" means performance of those adjustments or procedures specified in operator information provided by the manufacturer with the laser product, which are to be performed by the operator to ensure the intended performance of the product. The term does not include operation or service as defined in this Section.

"Maximum permissible exposure (MPE)" means the level of laser radiation to which a person may be exposed without hazardous effect or adverse biological changes in the eye or skin. MPE values for eye and skin exposure are listed in ANSI Z136.1-2000, American National Standard for Safe Use of Lasers, 2000 edition, which is incorporated by reference, published by the Laser Institute of America, 13501 Ingenuity Drive, Suite 128, Orlando, FL 32826, and on file with the Agency. This incorporation by reference contains no future editions or amendments.

"Medical laser product" means any laser product that is a medical device defined in 21 U.S.C. 321(h) and is manufactured, designed, intended, or promoted for in vivo laser irradiation of any part of the human body for the purpose of: diagnosis, surgery, therapy, or relative positioning of the human body.

"Operation" means the performance of the laser product over the full range of its function. It does not include maintenance or service as defined in this Section.

"Protective housing" means those portions of a laser product that are designed to prevent human access to laser or collateral radiation in excess of the prescribed accessible emission limits under conditions specified in this Article.

"Pulse duration" means the time increment measured between the half-peak-power points at the leading and trailing edges of a pulse.

"Pulse interval" means the period of time between identical points on two successive pulses.

"Radiance" means the time-averaged radiant power per unit area of a radiating surface per unit solid angle of emission, expressed in watts per square centimeter per steradian.

"Radiant energy" means energy emitted, transferred, or received in the form of radiation, expressed in joules.

"Radiant exposure" means the radiant energy incident on an element of a surface divided by the area of that element, expressed in joules per square centimeter.

"Radiant power" means the time-averaged power emitted, transferred, or received in the form of radiation, expressed in watts.

"Rule of nines" means a method for estimating the extent of burns, expressed as a percentage of total body surface. In this method the body is divided into sections of 9 percent or multiples of 9 percent, each: head and neck, 9 percent; anterior trunk, 18 percent; posterior trunk, 18 percent; upper limbs, 18 percent; lower limbs, 36 percent; and genitalia and perineum, 1 percent.

"Safety interlock" means a device associated with the protective housing of a laser product to prevent human access to excessive radiation.

"Sampling interval" means the time interval during which the level of accessible laser or collateral radiation is sampled by a measurement process. The magnitude of the sampling interval in units of seconds is represented by the symbol "t".

"Secured enclosure" means an area to which casual access is impeded by various means, such as a door secured by a lock, latch, or screws.

"Service" means the performance of those procedures or adjustments described in the manufacturer's service instructions that may affect any aspect of the product's performance. The term does not include maintenance or operation as defined in this Section.

"Tmax" See limited exposure duration.

"Uncertified laser product" means any laser that has not been certified in accordance with the requirements of 21CFR 1040.10, April 1, 2004, which is incorporated by reference, published by the Office of Federal Register National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. This incorporation by reference contains no future editions or amendments.

Radio frequency and microwave radiation definitions:

"Accessible emission level" means the level of radio frequency radiation emitted from any source, expressed in terms of power density in milliwatts per square centimeter or electric and magnetic field strength, as applicable, and to which human access is normally possible.

"Far field region" means the area in which locally uniform distribution of electric and magnetic field strengths exists in planes transverse to the direction of propagation. The far field region is presumed to exist at distances greater than $2D2/\lambda$ from the antenna, where λ is the wavelength and D is the largest antenna aperture dimension.

"Maximum permissible exposure MPE" means the rms and peak electric and magnetic field strengths, their squares, or the plane-wave equivalent power densities associated with these fields and the induced and contact currents to which a person may be exposed without harmful effect and with an acceptable safety factor.

"Near field region" means the area near an antenna in which the electric and magnetic field components vary considerably in strength from point to point. For most antennas the outer boundary of the region is presumed to exist at a distance $\lambda/2\pi$ from the antenna surface, where λ is the wavelength.

"Radio frequency controlled area" means any location to which access is controlled for the purpose of protection from radio frequency radiation.

"Radio frequency source" means a source or system that produces electromagnetic radiation in the radio frequency spectrum.

"Radio frequency radiation" means electromagnetic radiation (including microwave radiation) with frequencies in the range of 0.3 megahertz to 100 gigahertz.

"Root-mean-square (rms)" means the effective value, or the value associated with joule heating, of a periodic electromagnetic wave. The rms is obtained by taking the square root of the mean of the squared value of a function.

"Safety device" means any mechanism incorporated into a radio frequency source that is designed to prevent human access to excessive levels of radio frequency radiation.

Ultraviolet, high intensity light, and intense pulsed light source definitions:

"EPA" means the United States Environmental Protection Agency.

"FDA" means the United States Food and Drug Administration.
"High intensity mercury vapor discharge (HID) lamp" means any lamp, including a mercury vapor or metal halide lamp that incorporates a high-pressure arc discharge tube with a fill that consists primarily of mercury and is contained within an outer envelope, except the tungsten filament self-ballasted mercury vapor lamp.
"Intense pulsed light device (IPL)" means, for purposes of R12-1-1438, any lamp-based device that produces an incoherent, filtered, and intense light.
"Maximum exposure time" means the greatest continuous exposure time interval recommended by the manufacturer of a product.
"Protective sunlamp eyewear" means any device designed to be worn by a user of a product to reduce exposure of the eyes to radiation emitted by the product.
"Sanitize" means treat the surfaces of equipment and devices using an EPA or FDA registered product that provides a specified concentration of chemicals, for a specified period of time, to reduce the bacterial count, including pathogens, to a safe level.
"Self-extinguishing lamp" means any HID lamp that ceases operation in conformance with the requirements of the performance standard in 21 CFR 1040.30(d), April 1, 2004, which is incorporated by reference, published by the Office of Federal Register National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. This incorporation by reference contains no future editions or amendments.
"Sunlamp product" means any electronic product designed to incorporate one or more ultraviolet lamps and intended for irradiation of any part of the living human body, by ultraviolet radiation with wavelengths in air between 200 and 400 nanometers, to induce skin tanning.
"Timer" means any device incorporated into a product that terminates radiation emission after a preset time interval.
"Ultraviolet lamp" means any light source that produces ultraviolet radiation and that is intended for use in any sunlamp product.
"Ultraviolet radiation" means electromagnetic radiation in the wavelength interval from 200 to 400 nanometers in air.
"User" means any member of the public who is provided access to a tanning device in exchange for a fee or other compensation, or any individual who, in exchange for a fee or other compensation, is afforded use of a tanning device as a condition or benefit of membership or access.

Historical Note

Adopted effective April 2, 1990 (Supp. 90-2). Amended effective January 2, 1996 (Supp. 96-1). Amended by final rulemaking at 11 A.A.R. 61, effective February 5, 2005 (Supp. 04-4). Amended by final rulemaking at 11 A.A.R. 978, effective April 3, 2005 (05-1).

R12-1-1403. General Safety Provisions and Exemptions

A. Based on consideration of the following factors, the Agency may waive compliance with specific requirements of this Article:
   1. Whether compliance requires product replacement or substantial modification of a product's current installation, and
   2. Whether the registrant provided information requested by the Agency to determine if there are alternative methods of achieving the same or a greater level of radiation protection.

B. The registrant shall:
   1. Ensure that any nonionizing source is operated by an individual who is trained and has demonstrated competence in the safe use of the source.
   2. Provide safety rules to each individual who operates a nonionizing radiation source and determine whether the individual is aware of operating restrictions and procedures associated with the safe use of the source.
   3. Make, or cause to be made, any physical radiation surveys required by this Article.
   4. Maintain the following records for three years for Agency review:
      a. Results of any physical survey or calibration required by this Article;
      b. Radiation source inventories;
      c. Maintenance, service, and modification records; and
      d. Incident reports of known or suspected exposure to nonionizing radiation that exceeds any MPE specified in this Article.

C. A registrant shall not operate a nonionizing radiation source unless the source complies with all of the applicable requirements of this Article.

Historical Note

Adopted effective April 2, 1990 (Supp. 90-2). Section heading amended effective January 2, 1996 (Supp. 96-1). Amended by final rulemaking at 11 A.A.R. 61, effective February 5, 2005 (Supp. 04-4).

R12-1-1404. Radio Frequency Equipment

A. A registrant shall operate a radiation source that emits radio frequency radiation in a radio frequency controlled area, in a manner that will prevent human exposure that exceeds the MPE specified in IEEE Std C95.1-1999, Institute of Electrical and Electronics Engineers Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3kHz to 300 GHz, 1999 edition, which is incorporated by reference, published

by the Institute of Electrical and Electronic Engineers, Inc., 345 East 47th Street, New York, NY 10017, and on file with the Agency. This incorporation by reference contains no future editions or amendments. The registrant shall post each point of access into a radio frequency controlled area according to R12-1-1406.

B. If a registrant is required to operate a radio frequency source in a controlled area, the registrant shall employ visual or audible emission indicators that function only during production of radiation.

C. If a source of radio frequency emissions is physically separate from the source's means of activation by a distance greater than 2 meters, the registrant shall place a visual or an audible emission indicator at the source and the point of activation.

D. A registrant shall place each visual emission indicator so that the location of the indicator does not require human exposure to radio frequency radiation that exceeds the applicable MPE.

E. A registrant shall inspect each safety device designed to prevent human exposure to excessive radio frequency radiation for proper operation at intervals that do not exceed one month.

F. If a machine emits mechanically scanned radio frequency radiation, a registrant shall ensure that the machine cannot, as the result of scan failure or any other malfunction, cause a change in angular velocity or amplitude, allowing human exposure that exceeds the applicable MPE.

G. A registrant shall physically secure each radio frequency sources to prevent unauthorized use and tampering.

Historical Note

Adopted effective April 2, 1990 (Supp. 90-2). Amended effective January 2, 1996 (Supp. 96-1). Amended by final rulemaking at 11 A.A.R. 61, effective February 5, 2005 (Supp. 04-4).

R12-1-1405. Radio Frequency Radiation: Maximum Permissible Exposure

A. A registrant shall not expose a person to radio frequency radiation that exceeds the applicable MPE specified in IEEE Std C95.1-1999, Institute of Electrical and Electronics Engineers Standard for Safety Levels with Respect to Human Exposure to Radio Frequency Electromagnetic Fields, 3kHz to 300 GHz, 1999 edition, which is incorporated by reference, published by the Institute of Electrical and Electronic Engineers, Inc., 345 East 47th Street, New York, NY 10017, and on file with the Agency. This incorporation by reference contains no future editions or amendments.

B. At frequencies between 300 kHz and 100 GHz a registrant may exceed the applicable MPE if exposure conditions can be shown by laboratory procedures to produce specific absorption rates (SARs) above 0.4 watts per kilogram, averaged over the whole body, and spatial peak SAR values above 8 watts per kilogram, averaged over 1 gram of tissue.

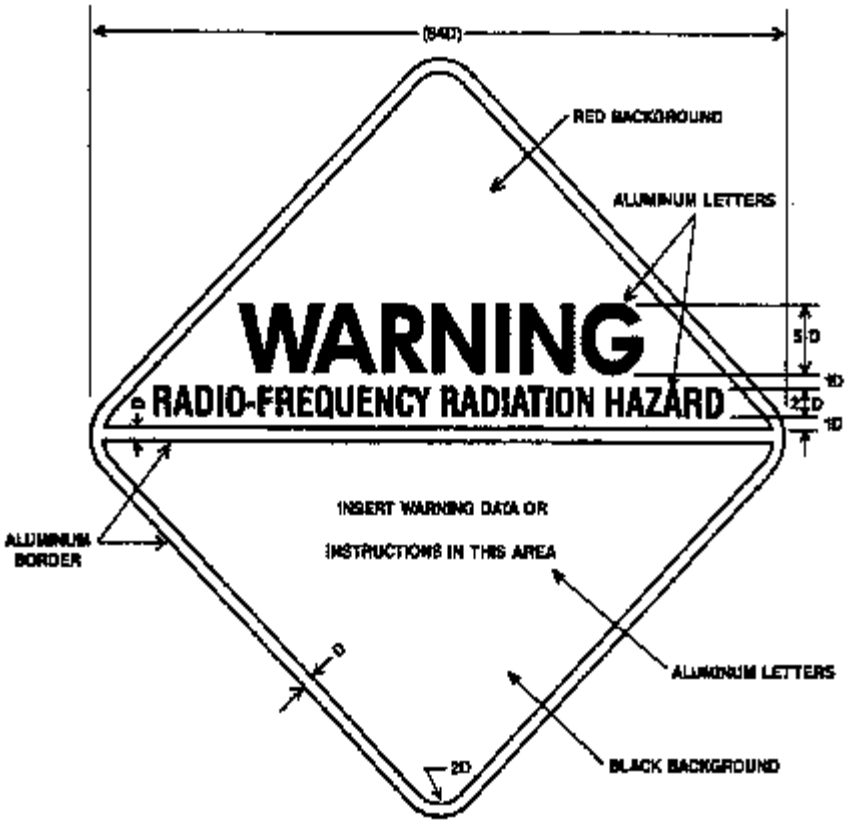
C. At frequencies between 300 kHz and 1 GHz, a registrant may exceed the applicable MPE, if the radio frequency input power to the radiating device is seven watts or less.

Historical Note

Adopted effective April 2, 1990 (Supp. 90-2). Amended effective January 2, 1996 (Supp. 96-1). Amended by final rulemaking at 11 A.A.R. 61, effective February 5, 2005 (Supp. 04-4).

R12-1-1406. Radio Frequency Hazard Caution Signs, Symbols, Labeling, and Posting

A. A registrant shall post each point of access to a controlled area with caution signs of the type designated in Figure 1.



1. Place handling and mounting instructions on reverse side.
2. D = Scaling unit.
3. Lettering: Ratio of letter height to thickness of letter lines.
   Upper triangle: 5 to 1 Large
   6 to 1 Medium
   Lower triangle: 4 to 1 Large
   6 to 1 Medium
4. Symbol is square, triangles are right-angle isosceles.

Fig.1

B. A registrant shall post operating procedure restrictions or limitations, used to prevent unnecessary or excessive exposure to radio frequency radiation, in a location visible to the operator.

C. A registrant shall place each warning sign or label so that an observer is not exposed to radio frequency radiation that exceeds the applicable MPE.

Historical Note

Adopted effective April 2, 1990 (Supp. 90-2). Section heading amended effective January 2, 1996 (Supp. 96-1). Amended by final rulemaking at 11 A.A.R. 61, effective February 5, 2005 (Supp. 04-4).

R12-1-1407. Microwave Ovens

A person shall register with the Agency any microwave oven that does not meet the requirements in 21 CFR 1030.10, April 1, 2004, which is incorporated by reference, published by the Office of Federal Register National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. This incorporation by reference contains no future editions or amendments.

Historical Note

Adopted effective April 2, 1990 (Supp. 90-2). Amended effective January 2, 1996 (Supp. 96-1). Amended by final rulemaking at 11 A.A.R. 61, effective February 5, 2005 (Supp. 04-4).

R12-1-1408. Reporting of Radio Frequency Radiation Incidents

A. A registrant shall report in writing to the Agency within 15 days of a known or suspected personnel exposure to radiation that exceeds the applicable MPE incorporated by reference in R12-1-1405.

B. A registrant shall report to the Agency within 24 hours of a known or suspected personnel exposure to radiation that exceeds 150% of an applicable MPE incorporated by reference in R12-1-1405.

C. A registrant shall immediately report to the Agency a known or suspected personnel exposure to radiation that exceeds 500% of an applicable MPE incorporated by reference in R12-1-1405.

Historical Note

Adopted effective April 2, 1990 (Supp. 90-2). Amended effective January 2, 1996 (Supp. 96-1). Amended by final rulemaking at 11 A.A.R. 61, effective February 5, 2005 (Supp. 04-4).

R12-1-1409. Medical Surveillance for Workers Who May Be Exposed to Radio Frequency Radiation

A. Upon request by the Agency, a registrant shall provide a medical examination to an individual exposed to radiation reported to the Agency according to R12-1-1408.

B. A registrant shall provide a copy of the results to the Agency if an individual undergoes a medical examination, requested under subsection (A).

Historical Note

Adopted effective April 2, 1990 (Supp. 90-2). Section heading amended effective January 2, 1996 (Supp. 96-1). Amended by final rulemaking at 11 A.A.R. 61, effective February 5, 2005 (Supp. 04-4).

R12-1-1410. Radio Frequency Compliance Measurements

A. For obtaining measurements to determine compliance with R12-1-1405, the Agency shall use an instrument capable of measuring the field strength and frequency of radiation.

B. The Agency shall ensure that each instrument used for compliance measurements is calibrated every 12 months. The calibration shall be performed in a manner that meets the standards in IEEE Std C95.1-1999, incorporated by reference in R12-1-1404(A).

C. For compliance measurements of exposure conditions in the near field, the Agency shall obtain measurements of both the electric and magnetic field components. The applicable protection standards for near field measurements are the mean squared electric and magnetic field strengths (using the applicable MPE) referenced in R12-1-1405.

D. If the Agency is obtaining measurements to determine compliance in far field exposure conditions, the Agency may use measurements of power density in milliwatts per square centimeter or the calculated equivalent plane wave power density, based on measurement of either the electric or magnetic field strength. The applicable protection standards are the power density values (using the applicable MPE) referenced in R12-1-1405.

E. In obtaining measurements in accordance with this Section, the Agency shall measure the electric and magnetic field strength:

1. Obtained at an emission frequency of 300 megahertz or less; and
2. Expressed in terms of power density.

F. For mixed or broadband fields at frequencies for which there are different protection standards, the Agency shall determine the fraction of the applicable MPE incurred within each frequency interval. To achieve compliance the sum of all the fractions shall not exceed unity (1).

G. The Agency shall obtain compliance measurements at a distance of five centimeters or greater from any object.

H. A registrant shall obtain measurements that are averaged over a six-minute period for pulsed and non-pulsed modes of radio frequency emission and make a correction for duty cycle in determining the average field strength.

Historical Note

Adopted effective April 2, 1990 (Supp. 90-2). Amended effective January 2, 1996 (Supp. 96-1). Amended by final rulemaking at 11 A.A.R. 61, effective February 5, 2005 (Supp. 04-4).

R12-1-1411. Repealed

Historical Note

Adopted effective April 2, 1990 (Supp. 90-2). Amended effective January 2, 1996 (Supp. 96-1). Section repealed by final rulemaking at 11 A.A.R. 61, effective February 5, 2005 (Supp. 04-4).

R12-1-1412. Tanning Operations

A registrant shall establish and maintain written policies and procedures that are part of a radiation safety program to assure compliance with the requirements in R12-1-1412 through R12-1-1416.

Historical Note

Adopted effective April 2, 1990 (Supp. 90-2). Amended effective January 2, 1996 (Supp. 96-1). Amended by final rulemaking at 11 A.A.R. 61, effective February 5, 2005 (Supp. 04-4).

R12-1-1413. Tanning Equipment Standards

A. A registrant operating a tanning facility shall use sunlamp products that are certified by the manufacturer to comply with 21 CFR 1040.20, April 1, 2004, which is incorporated by reference, published by the Office of Federal Register National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. This incorporation by reference contains no future editions or amendments. For sunlamp products in use before the effective date of this Article, the Agency shall determine compliance based on the standard in effect at the time of manufacture, as shown on the equipment identification label.

B. A registrant shall replace burned-out or defective lamps or filters, before any use of a tanning device.

C. A registrant shall replace a burned-out or defective lamp or filter with a lamp or filter intended for use in that equipment, as specified on the sunlamp product label, or that is equivalent to a lamp or filter specified on the sunlamp product label under the FDA regulations and polices applicable to the sunlamp product at the time of manufacture. If an equivalent lamp or filter is used instead of the Original Equipment Manufacturer (OEM) lamp or filter specified on the product label, the registrant shall maintain a copy of the equivalency certification, provided by the lamp supplier, on file for review by Agency inspectors.

D. A registrant shall ensure that each sunlamp product has a timer and control system that complies with 21 CFR 1040.20(c), April 1, 2004, which is incorporated by reference, published by the Office of Federal Register National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. This incorporation by reference contains no future editions or amendments. In addition the registrant shall ensure that:

1. The timer interval does not exceed the manufacturer's maximum, recommended exposure time;
2. The timer is functional and accurate to within +/- 10% of the maximum timer interval of the product;
3. The timer does not automatically reset and cause radiation emission to resume for a period greater than the unused portion of the timer cycle;
4. The timer is tested annually for accuracy;
5. For a new facility (including existing facilities with change of ownership) a remote timer control system is installed before operation of sunlamp products. For an existing facility that has sunlamp products not equipped with a remote timer control system, a remote timer control system (outside of the sunlamp product room) is installed no later than 6 months after the effective date of this Section; and
6. Each sunlamp product is equipped with an emergency shutoff mechanism that allows manual termination of the UV exposure by the user.

E. A registrant shall provide physical barriers between each sunlamp product to protect users from injury caused by touching or breaking a lamp.

F. A registrant that employs a stand-up sunlamp product shall:

1. Use physical barriers, handrails, floor markings, or other methods to indicate the proper exposure distance between the ultraviolet lamps and the user's skin;
2. Construct each tanning booth so that it can withstand the stress of use and the impact of a falling person;
3. Provide access to a tanning booth with doors of rigid construction that open outward, handrails, and non-slip floors; and
4. Control the interior temperature of a sunlamp product so that it never exceeds 100 degrees Fahrenheit (38 degrees Centigrade).

Historical Note

Adopted effective April 2, 1990 (Supp. 90-2). Amended effective January 2, 1996 (Supp. 96-1). Amended by final rulemaking at 11 A.A.R. 61, effective February 5, 2005 (Supp. 04-4).

R12-1-1414. Tanning Equipment Operators

A. A registrant shall ensure that at least one operator is present during operating hours. The operator shall:

1. Limit the occupancy of the tanning room to one person when the tanning equipment is in use;
2. Prevent use of the tanning equipment by anyone under 18 years of age unless the person has written permission from a parent or guardian;
3. Limit exposure time to the manufacturer's recommendation on the equipment label or in the operator's manual;
4. Limit exposure time during a 24-hour period to the maximum recommended for a 24-hour period by the manufacturer; and
5. Maintain a record of each user's total number of tanning visits and exposure times for Agency inspection. The registrant shall maintain the records for three years from the date on the record.

B. Before use of tanning equipment, an operator shall:

1. Provide the user sanitized protective sunlamp eyewear and directions for its use;
2. Demonstrate the use of any physical aids, necessary to maintain correct exposure distance for the user, as recommended by the manufacturer of the tanning equipment;
3. Set the exposure timer so that the user is not exposed to excess radiation;
4. Instruct the user on the maximum exposure time and correct distance from the radiation source as recommended by the manufacturer of the tanning equipment; and
5. Instruct the user about the location and correct operation of the emergency shutoff switch.

C. An operator shall control a sunlamp's timer. A registrant shall:

1. Provide training to operators that covers:
    a. The requirements of this Section;
    b. Facility operating procedures, including:
        i. Determination of skin type and associated duration of exposure;
        ii. Procedures for use of minor and adult user consent forms;
        iii. Potential harm associated with photosensitizing foods, cosmetics, and medications;
        iv. Requirements for use of protective eyewear by users of the equipment; and
        v. Proper sanitizing procedures for the facility, equipment, and eyewear;

c. The manufacturer's procedures for operation and maintenance of tanning equipment;
d. Recognition of injury or overexposure; and
e. Emergency procedures used in the case of an injury.

2. Maintain records of training for Agency review, which include dates and material covered, for three years from the date the training is provided.
3. Post a list of operators at the facility.

D. Before the first use of a tanning facility in each calendar year by a user:
1. An operator shall request that the user read a copy of the warnings in R12-1-1415(A);
2. The operator shall obtain the user's signature on a statement as an acknowledgment that the user has heard or read and understands the warnings in R12-1-1415(A); and
3. For illiterate or visually handicapped persons, the operator shall read the warnings in R12-1-1415(A) in the presence of a witness. Both the witness and the operator shall sign the statement described in subsection (D)(2).

Historical Note

Adopted effective April 2, 1990 (Supp. 90-2). Amended effective January 2, 1996 (Supp. 96-1). Amended by final rulemaking at 11 A.A.R. 61, effective February 5, 2005 (Supp. 04-4).

R12-1-1415. Tanning Facility Warning Signs

A. A registrant shall post the warning sign shown in this subsection within 1 meter (39.37 inches) of each tanning device, ensuring that the sign is clearly visible and easily viewed by the user before the tanning device is operated.

B. A registrant shall post a warning sign, which contains the statement shown, at or near the reception area.

PERSONS UNDER AGE 18 ARE REQUIRED TO HAVE PARENT OR LEGAL GUARDIAN SIGN AN AUTHORIZATION TO TAN IN THE PRESENCE OF A TANNING FACILITY OPERATOR

C. The lettering on each warning sign shall be at least 10 millimeters high for all words shown in capital letters and at least 5 millimeters high for all lower case letters.

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DANGER - ULTRAVIOLET RADIATION

1. Follow instructions.
2. Avoid overexposure. As with natural sunlight, exposure can cause eye and skin injury and allergic reactions. Repeated exposure may cause premature aging of the skin, dryness, wrinkling, and skin cancer.
3. Wear protective eyewear.

FAILURE TO USE PROTECTIVE EYEWEAR MAY RESULT IN SEVERE BURNS OR LONG TERM INJURY TO THE EYES.

4. Medications or cosmetics may increase your sensitivity to the ultraviolet radiation. Consult a physician before using a sunlamp if you are using medications or have a history of skin problems or believe you are especially sensitive to sunlight.
5. If you do not tan in the sun, you are unlikely to tan from use of this device.

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Historical Note

Adopted effective April 2, 1990 (Supp. 90-2). Section heading amended effective January 2, 1996 (Supp. 96-1). Amended by final rulemaking at 11 A.A.R. 61, effective February 5, 2005 (Supp. 04-4).

R12-1-1416. Reporting of Tanning Injuries

A. A registrant shall report any incident involving an eye injury; skin burn; fall injury, if the fall occurs within the tanning device or while entering or exiting the device; laceration; infection believed to have been transmitted by use of the tanning device; or any other injury reasonably related to the use of the tanning device.

B. A registrant shall provide a written report of an incident to the Agency within 10 working days of its occurrence or within 10 working days of the date the registrant became aware of the incident.

C. The report shall include:
1. The name of the user;
2. The name and location of the tanning facility;
3. A description of and the circumstances associated with the injury;
4. The name and address of the health care provider treating the user, if any; and
5. Any other information the registrant considers relevant to the incident.

Historical Note

Adopted effective April 2, 1990 (Supp. 90-2). Amended by final rulemaking at 11 A.A.R. 61, effective February 5, 2005 (Supp. 04-4).

R12-1-1417. Repealed

Historical Note

Adopted effective April 2, 1990 (Supp. 90-2). Section repealed by final rulemaking at 11 A.A.R. 61, effective February 5, 2005 (Supp. 04-4).

R12-1-1418. High Intensity Mercury Vapor Discharge (HID) Lamps

A person shall register with the Agency any HID lamp that does not meet the requirements in 21 CFR 1040.30, April 1, 2004, which is incorporated by reference, published by the Office of Federal Register National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. This incorporation by reference contains no future editions or amendments.

Historical Note

New Section made by final rulemaking at 11 A.A.R. 61, effective February 5, 2005 (Supp. 04-4).

R12-1-1419. Reserved

R12-1-1420. Reserved

R12-1-1421. Laser Safety

A. The requirements contained in this Section apply to laser products that are used in accordance with the manufacturer's classification and instructions. If certain engineering controls are impractical during manufacture or research and development activities, the LSO shall specify alternate requirements to obtain equivalent laser safety protection.

B. A registrant shall establish and maintain a laser radiation safety program.

C. If R12-1-1433 is applicable, a registrant shall conduct a laser radiation protection survey to ensure compliance with R12-1-1433 before initial use, following system modifications, and at intervals that do not exceed six months. During a survey the registrant shall:

1. Determine whether each laser protective device is labeled correctly, functioning within the design specifications, and meets required standards for the type and class of laser in use;
2. Determine whether each warning device is functioning within design specifications;
3. Determine whether each controlled area is identified, controlled, and posted with accurate warning signs in accordance with this Article;
4. Reevaluate potential hazards from surfaces that are associated with Class 3 and Class 4 beam paths; and
5. Evaluate the laser and collateral radiation hazard incident to the use of lasers.

D. The registrant shall maintain records of:

1. Results of all physical surveys made to determine compliance with this Article;
2. Any restriction in operating procedures necessary to prevent unnecessary or excessive exposure to laser or collateral radiation;
3. Any incident for which reporting to the Agency is required pursuant to R12-1-1436;
4. Results of medical surveillance to determine extent of injury resulting from exposure to laser or collateral radiation;
5. Inventory to account for all sources of radiation possessed by the licensee.

E. A registrant shall provide the Laser Safety Officer with training that covers the subjects listed in Appendix D.

Historical Note

Adopted effective April 2, 1990 (Supp. 90-2). Amended effective January 2, 1996 (Supp. 96-2). Amended by final rulemaking at 11 A.A.R. 61, effective February 5, 2005 (Supp. 04-4). Amended by final rulemaking at 11 A.A.R. 978, effective April 3, 2005 (Supp. 05-1).

R12-1-1422. Laser Protective Devices

A. A registrant shall ensure that each laser product has a protective housing that prevents access to laser and collateral radiation if it exceeds the exposure limits for Class 1 lasers in R12-1-1426. If a laser's accessible emission levels must exceed the limits for Class 1 lasers, the registrant shall use a laser from the lowest class that will enable the registrant to perform the intended function.

B. To prevent access to radiation above the applicable MPE, a registrant shall ensure that each laser has a safety interlock, which prevents operation of the laser if a person has removed any portion of the protective housing that can be removed or displaced without the use of tools during normal operation or maintenance. The registrant shall ensure that:

1. Service, testing, or maintenance of a laser does not render the interlocks inoperative or increase radiation outside the protective housing to levels that exceed the applicable MPE, unless a controlled area is established as specified in R12-1-1433;
2. For pulsed lasers, interlocks are designed to prevent the laser from firing;
3. For Class 3b and 4 continuous wave (cw) lasers, interlocks turn off the power supply or interrupt the beam.
4. An interlock does not allow automatic accessibility to radiation emission above the applicable MPE when the interlock is closed; and
5. Multiple safety interlocks or a means to preclude removal or displacement of the interlocked portion of the protective housing is provided if failure of a single interlock could result in:

a. Human access to levels of laser radiation that exceed the radiant power accessible emission limit for Class 3a laser radiation, or

b. Laser radiation that exceeds the accessible emission limit for Class 2, emitted directly through the opening created by removal or displacement of a portion of the protective housing.

C. A registrant shall ensure that a laser with viewing ports, viewing optics, or display screens, included as an integral part of the enclosed laser or laser system has:

1. A suitable means to attenuate laser and collateral radiation transmitted through the optical system to less than the accessible emission limit for collateral radiation required by 21 CFR 1040.10, April 1, 2004, which is incorporated by reference, published by the Office of Federal Register National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. This incorporation by reference contains no future editions or amendments; and
2. Specific written administrative procedures developed by the LSO, and use controls, such as interlocks or filters, if there is increased hazard to the eye or skin associated with the use of optical systems such as lenses, telescopes, or microscopes.

D. A registrant shall ensure that each Class 3 or 4 laser product provides a visual or audible indication before the emission of accessible laser radiation that exceeds the limits for Class 1, as follows:

1. For Class 3, except for laser products that allow access to less than 5 milliwatts peak visible laser radiation, and Class 4 lasers, the indication occurs before the emission of the radiation and allows enough time for action to avoid exposure;
2. Any visual indicator is clearly visible through protective eyewear designed specifically for the wavelength of the emitted laser radiation;
3. If the laser and laser energy source are housed separately and can be operated at a separation distance of greater than 2 meters, both the laser and laser energy source incorporate visual or audible indicators; and
4. Any visual indicators are positioned so that viewing does not require human access to laser radiation that exceeds the applicable MPE.

E. In addition to the information signs, symbols, and labels prescribed in R12-1-1427, R12-1-1428, and R12-1-1429, each registrant shall provide, near the signs, symbols, and labels within the laser facility, operating procedure restrictions and any other safety information required to ensure compliance with this Article and minimize exposure to laser and collateral radiation.

Historical Note

Adopted effective April 2, 1990 (Supp. 90-2). Table referenced in subsection (A) was repealed effective January 2, 1996; Section amended effective January 2, 1996 (Supp. 96-1). Amended by final rulemaking at 11 A.A.R. 61, effective February 5, 2005 (Supp. 04-4).

R12-1-1423. Laser Prohibitions

A. A registrant shall not require or permit an individual to look directly into a laser beam or directly at specular reflections of a laser beam, or align a laser by eye while looking along the axis of the laser beam if the intensity of the beam or the beam's reflections exceeds the applicable MPE.

B. A registrant shall not permit an individual to enter a controlled area if the skin exposure exceeds the applicable MPE, unless the registrant provides and requires the use of protective clothing, gloves, and shields.

C. A registrant shall ensure that any laser product, emitting spatially scanned laser radiation, does not, as a result of scan failure or any other failure that causes a change in angular velocity or amplitude, permit human access to laser radiation that exceeds the accessible emission limits applicable to that class of product.

Historical Note

Adopted effective April 2, 1990 (Supp. 90-2). Amended by final rulemaking at 11 A.A.R. 61, effective February 5, 2005 (Supp. 04-4).

R12-1-1424. Repealed

Historical Note

Adopted effective April 2, 1990 (Supp. 90-2). Repealed effective January 2, 1996 (Supp. 96-1).

R12-1-1425. Laser Product Classification

A. Each laser product is classified on the basis of emission level, emission duration, and wavelength of accessible laser radiation emitted over the full range of resulting operational capability, any time during the useful life of the product, according to the federal performance standards for light-emitting products contained in 21 CFR 1040.10, April 1, 2004, which is incorporated by reference, published by the Office of Federal Register National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. This incorporation by reference contains no future editions or amendments.

B. Any person that modifies a certified laser product in a manner that affects any aspect of performance or intended functions of the product, shall recertify and reidentify the product in accordance with 21 CFR 1040.10, April 1, 2004, which is incorporated by reference, published by the Office of Federal Register National Archives and

Records Administration, Washington, D.C. 20408, and on file with the Agency. This incorporation by reference contains no future editions or amendments.

C. Any laser system that is incorporated into a laser product that is subject to the requirements of this Article, and capable, without modification, of producing laser radiation when removed from the laser product, is considered a laser product, subject to the applicable requirements of this Article. Upon removal of the laser system described in this subsection, the laser product is classified on the basis of accessible laser radiation emission.

Historical Note

Adopted effective April 2, 1990 (Supp. 90-2). Amended effective January 2, 1996 (Supp. 96-1). Amended by final rulemaking at 11 A.A.R. 61, effective February 5, 2005 (Supp. 04-4).

R12-1-1426. Laser and Collateral Radiation Exposure Limits

A. A registrant shall not use, or permit the use of a laser product that will result in a human exposure that exceeds the applicable MPE or accessible emission limit (AEL) listed in ANSI Z136.1-2000, American National Standard for Safe Use of Lasers, 2000 edition, which is incorporated by reference, published by the Laser Institute of America, 13501 Ingenuity Drive, Suite 128, Orlando, FL 32826, and on file with the Agency. Accessible emission limits are listed in 21 CFR 1040.10, April 1, 2004, which is incorporated by reference, published by the Office of Federal Register National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. These incorporations by reference contain no future editions or amendments.

B. A registrant shall not allow exposure to collateral radiation that exceeds any accessible emission limit in 21 CFR 1040.10, April 1, 2004, which is incorporated by reference, published by the Office of Federal Register National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. This incorporation by reference contains no future editions or amendments.

Historical Note

Adopted effective April 2, 1990 (Supp. 90-2). Amended effective January 2, 1996 (Supp. 96-1). Amended by final rulemaking at 11 A.A.R. 61, effective February 5, 2005 (Supp. 04-4).

R12-1-1427. Laser Caution Signs, Symbols, and Labels

A. Except as otherwise authorized by the Agency, a registrant shall use signs, symbols, and labels prescribed by this Section and the design and colors specified in ANSI Z136.1-2000, American National Standard for Safe Use of Lasers, 2000 edition, which is incorporated by reference, published by the Laser Institute of America, 13501 Ingenuity Drive, Suite 128, Orlando, FL 32826, and on file with the Agency. This incorporation by reference contains no future editions or amendments.

B. A registrant shall ensure that the word "invisible" immediately precedes the word "radiation" on labels and signs required by this Section for lasers that only produce wavelengths of laser and collateral radiation that are outside of the range of 400 to 710 nanometers.

C. A registrant shall ensure that the words "visible and invisible" immediately precede the word "radiation" on labels and signs required by this Section for lasers that produce wavelengths of laser and collateral radiation that are both within and outside the range of 400 to 710 nanometers.

D. A registrant shall position any label placed on lasers or signs posted in laser facilities so that the reader of the label or sign is not exposed to laser or collateral radiation that exceeds the applicable MPE or accessible emission limit while reading the label or sign.

E. A registrant shall use labels and signs that are clearly visible, legible, and permanently attached to the laser or facility.

F. A registrant shall ensure that a permanent and legible label is affixed to each laser, identifying the classification of the laser in accordance with 21 CFR 1040.10, April 1, 2004, which is incorporated by reference, published by the Office of Federal Register National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. This incorporation by reference contains no future editions or amendments.

G. For a Class 3 or Class 4 laser a registrant shall ensure that a permanent and legible label is affixed to each laser, specifying the maximum output of laser radiation, the pulse duration if applicable, and the laser medium or emitted wavelength.

H. For a Class 3 or Class 4 laser, used in the practice of medicine, a registrant shall ensure that a permanent and legible label is affixed to each laser providing one or more of the following warnings near each aperture that emits laser radiation or collateral radiation that exceeds the applicable MPE, as follows:

1. "AVOID EXPOSURE - Laser radiation is emitted from this aperture" if the radiation emitted through the aperture is laser radiation;
2. "AVOID EXPOSURE - Hazardous electromagnetic radiation is emitted from this aperture" if the radiation emitted through the aperture is collateral radiation; or
3. "AVOID EXPOSURE - Hazardous x-rays are emitted from this aperture" if the radiation emitted through the aperture is collateral x-ray radiation.

I. A registrant shall ensure that there is a label on each non-interlocked or defeatable interlocked portion of the protective housing or enclosure that permits human access to laser or collateral radiation. The label shall include one or more of the following warnings, as applicable:

1. For laser radiation that exceeds the applicable accessible emission limit for a Class 1 or Class 2 laser, but does not exceed the applicable accessible emission limit for a Class 3 laser, the warning: "DANGER - Laser radiation when open, AVOID DIRECT EXPOSURE TO THE BEAM."
2. For laser radiation that exceeds the applicable accessible emission limit for a Class 3 laser, the warning: "DANGER - Laser radiation when open, AVOID EYE OR SKIN EXPOSURE TO DIRECT OR SCATTERED RADIATION."
3. For collateral radiation that exceeds an applicable accessible emission limit:
   a. If the applicable limit for collateral laser radiation is exceeded, the warning: "CAUTION - Hazardous electromagnetic radiation when open"; and
   b. If the applicable limit for collateral x-ray radiation is exceeded, the warning: "CAUTION - Hazardous x-ray radiation".
4. For a protective housing or an enclosure that has a defeatable interlock, the warning "and interlock defeated" in addition to the warnings in subsections (1) through (3).

Historical Note

Adopted effective April 2, 1990 (Supp. 90-2). Amended effective January 2, 1996 (Supp. 96-1). Amended by final rulemaking at 11 A.A.R. 61, effective February 5, 2005 (Supp. 04-4).

R12-1-1428. Repealed

Historical Note

Adopted effective April 2, 1990 (Supp. 90-2). Repealed effective January 2, 1996 (Supp. 96-1).

R12-1-1429. Posting of Laser Facilities

Unless other methods are approved by the Agency, a registrant shall post each laser facility in accordance with ANSI Z136.1-2000, American National Standard for Safe Use of Lasers, 2000 edition, which is incorporated by reference, published by the Laser Institute of America, 13501 Ingenuity Drive, Suite 128, Orlando, FL 32826, and on file with the Agency. This incorporation by reference contains no future editions or amendments.

Historical Note

Adopted effective April 2, 1990 (Supp. 90-2). Amended effective January 2, 1996 (Supp. 96-1). Amended by final rulemaking at 11 A.A.R. 61, effective February 5, 2005 (Supp. 04-4).

R12-1-1430. Repealed

Historical Note

Adopted effective April 2, 1990 (Supp. 90-2). Repealed effective January 2, 1996 (Supp. 96-1).

R12-1-1431. Repealed

Historical Note

Adopted effective April 2, 1990 (Supp. 90-2). Repealed effective January 2, 1996 (Supp. 96-1).

R12-1-1432. Repealed

Historical Note

Adopted effective April 2, 1990 (Supp. 90-2). Repealed effective January 2, 1996 (Supp. 96-1).

R12-1-1433. Laser Use Areas that are Controlled

A. A registrant shall establish a controlled area for a laser if it is possible for a person to be exposed to laser radiation from a Class 3b laser, except a Class 3b laser of less than 5 milliwatts visible peak power, or a Class 4 laser that exceeds the applicable MPE or AEL in R12-1-1426.

B. A registrant shall ensure that a controlled area associated with a Class 3b laser is:
   1. The responsibility of a LSO;
   2. Posted in accordance with this Article; and
   3. Access controlled by the LSO or a trained, designated representative.

C. A registrant shall ensure that a controlled area associated with a Class 4 laser is:
   1. The responsibility of a LSO;
   2. Posted in accordance with this Article;
   3. Access controlled by the LSO or a trained, designated representative; and
   4. If an indoor controlled area:
      a. Equipped with latches, interlocks, or another means of preventing unexpected entry into the controlled area;
      b. Equipped with a control-disconnect switch, panic button, or an equivalent device for deactivating the laser during an emergency;
      c. Operated so that the person in charge of the controlled area can momentarily override the safety interlocks during tests that require continuous operation to provide access to other personnel if there is no optical

radiation hazard at the point of entry and the entering personnel are wearing required protective devices; and

d. Controlled in a way that reduces the transmitted values of laser radiation through optical paths such as windows, to levels at or below the applicable ocular MPE and AEL in R12-1-1426. If a laser beam with an irradiance or radiant-exposure above the applicable MPE or AEL will exit the indoor controlled area (as in the case of exterior atmospheric beam paths), the registrant and the operator are responsible for ensuring that the beam path is limited to controlled air space or controlled ground space.

D. If a panel or protective cover is removed or an interlock bypassed for service, testing, or maintenance, a registrant shall establish an accessible controlled area. The registrant, through a LSO or a designated representative, shall comply with laser safety requirements for all potentially-exposed individuals.

Historical Note

Adopted effective April 2, 1990 (Supp. 90-2). Amended effective January 2, 1996 (Supp. 96-1). Amended by final rulemaking at 11 A.A.R. 61, effective February 5, 2005 (Supp. 04-4).

R12-1-1434. Laser Safety Officer (LSO)

A. Each registrant shall designate a Laser Safety Officer (LSO).

B. The LSO shall administer the laser radiation protection program and shall:

1. Ensure that maintenance or service for Class 3b and Class 4 lasers is performed only by technicians trained to provide the maintenance or service by either the manufacturer's service organization or the registrant;
2. Approve or reject written service, maintenance, and operating procedures;
3. Investigate, document, and report all incidents as required by R12-1-1436;
4. Select protective eyewear as required by R12-1-1435, along with any other protective equipment;
5. For health care facilities, establish authorization and operating procedures, including preoperative and postoperative checklists, for use by operating room personnel;
6. Ensure that authorized personnel are trained in the assessment and control of laser hazards;
7. Select signs, symbols, and labels as required by R12-1-1427;
8. Perform laser radiation protection surveys as required by R12-1-1421 and R12-1-1441;
9. Classify or verify the classification of lasers and laser systems used under the LSO's jurisdiction;
10. Evaluate the hazard of laser use areas, treatment areas, and controlled areas, as required by R12-1-1421(C).

Historical Note

Adopted effective April 2, 1990 (Supp. 90-2). Amended by final rulemaking at 11 A.A.R. 61, effective February 5, 2005 (Supp. 04-4).

R12-1-1435. Laser Protective Eyewear

A. A registrant shall require that protective eyewear, as specified by the LSO, be worn by an individual who has access to:

1. Class 4 laser radiation; or
2. Class 3b laser radiation.

B. A registrant shall, through the LSO, provide protective eyewear that is:

1. Marked with a label that indicates the optical density protection afforded for the relevant laser wavelength;
2. Maintained so that the protective properties of the eyewear are preserved;
3. Inspected at intervals that do not exceed six months to ensure integrity of the protective properties; and
4. Removed from service if the protective properties of the eyewear fall below the optical density on the label.

C. A registrant shall maintain records of protective eyewear maintenance, inspection, and removal from service for five years.

Historical Note

Adopted effective April 2, 1990 (Supp. 90-2). Section heading amended effective January 2, 1996 (Supp. 96-1). Amended by final rulemaking at 11 A.A.R. 61, effective February 5, 2005 (Supp. 04-4).

R12-1-1436. Reporting Laser Incidents

A. A registrant shall notify the Agency by telephone within 24 hours of any incident that has caused or may have caused:

1. Permanent loss of sight in either eye; or
2. Third-degree burns of the skin involving more than 5 percent of the body surface as estimated by the rule of nines.

B. A registrant shall notify the Agency by telephone within five working days of any incident that has or may have caused:

1. Any second-degree burn of the skin larger than one inch (2.54 centimeter) in greatest diameter; or
2. Any third-degree burn of the skin; or
3. An eye injury with any potential loss of sight.

C. Each registrant shall file a written report with the Agency of any known exposure of an individual to laser radiation or collateral radiation within 30 days of its discovery, describing:

1. Each exposure of the individual to laser or collateral radiation that exceeds the applicable MPE; and
2. Any incident that triggered a notice requirement in subsections (A) or (B).

D. Each report required by subsection (C) shall describe the extent of exposure to each individual including:
1. An estimate of the individual's exposure;
2. The level of laser or collateral radiation involved;
3. The cause of the exposure; and
4. The corrective steps taken or planned to prevent a recurrence.

E. A registrant shall not operate or permit the operation of any laser product or system that does not meet the applicable requirements in this Article.

Editor's Note: The tables referenced in subsection (A) were repealed effective January 2, 1996.

Historical Note

Adopted effective April 2, 1990 (Supp. 90-2). Amended effective January 2, 1996 (Supp. 96-1); the tables previously referenced in subsection (A) were repealed effective January 2, 1996 (Supp. 96-1). Amended by final rulemaking at 11 A.A.R. 61, effective February 5, 2005 (Supp. 04-4).

R12-1-1437. Special Lasers

A registrant operating a laser system with an unenclosed beam path shall:
1. Conduct an evaluation before operating the laser to determine the expected beam path and the potential hazards from reflective surfaces. Based on the evaluation the registrant shall exclude reflective surfaces from the beam path at all points where the laser radiation exceeds an applicable MPE;
2. Evaluate the stability of the laser platform to determine the constraints placed upon the beam traverse and the extent of the range of control; and
3. Refrain from operating or making a laser ready for operation until the area along all points of the beam path, where the laser radiation will exceed the applicable MPE, is clear of individuals, unless the individuals are wearing the correct protective devices.

Historical Note

Adopted effective April 2, 1990 (Supp. 90-2). Amended effective January 2, 1996 (Supp. 96-1). Amended by final rulemaking at 11 A.A.R. 61, effective February 5, 2005 (Supp. 04-4).

R12-1-1438. Hair Reduction and Other Cosmetic Procedures Using Laser and Intense Pulsed Light

A. Registration. A person who seeks to perform hair reduction or other cosmetic procedures shall apply for registration of any medical laser or IPL device that is a Class II surgical device, certified as complying with the labeling standards in 21 CFR 801.109, revised April 1,2010, incorporated by reference and available under R12-1-101. This incorporated material contains no future editions or amendments. The applicant shall provide all of the following information to the Agency with the application for registration:
1. Documentation demonstrating that health professional is qualified in accordance with A.R.S. § 32-516 or A.R.S. § 32-3233, has 24 hours of didactic training on the subjects listed in Appendix C, and has passed an Agency-approved exam on subjects covered with a minimum grade of 80%;
2. For any health professional in practice prior to October 1, 2010, proof of 24 hours of training on the subjects listed in Appendix C;
3. Documentation endorsed by the prescribing health professional, acknowledging responsibility for the minimum level of supervision required for hair reduction procedures as defined in R12-1-1402 under "indirect supervision";
4. Procedures to ensure that the registrant has a written order from a prescribing health professional before the application of radiation;
5. If authorized, procedures to ensure that, in the absence of a prescribing health professional at the facility, the registrant has established a method for emergency medical care and assumed legal liability for the service rendered by an indirectly-supervised certified laser technician; and
6. Documentation that the indirectly-supervised certified laser technician has participated in the supervised training required by A.R.S. § 32-516 or A.R.S. § 32-3233.

B. Hair Reduction Procedures
1. If a registrant is using a medical laser or an IPL device that is a Class II surgical device, certified in accordance with the labeling standards in subsection (A), for hair reduction procedures, the registrant shall:
   a. Ensure that the device is only used by a health professional described in A.R.S. §§32-516(F)(3) and 32-3233(D)(1) or by a certified laser technician who is working under the indirect supervision of a health professional described in A.R.S. §§ 32-516(C)(1) and 32-3233(D) and (H)(1), and
   b. Ensure that a prescribing health professional purchases or orders the Class II surgical device that will be used for hair reduction procedures.
2. A registrant shall:
   a. Not permit an individual to use a medical laser or IPL device for hair reduction procedures unless the individual:

i. Completes an approved laser technician didactic training program of at least 40 hours duration. To successfully complete the training program, the individual shall pass a test that consists of at least 50 multiple choice questions on subjects covered with a minimum grade of 80%. The training program shall be provided by an individual who is a health professional acting within their scope of practice, or a certified laser technician with a minimum of 100 hours of hands-on experience per procedure being taught;

ii. Is present in the room for at least 24 hours of hands-on training, conducted by health professional or a certified laser technician as described in subsection (B)(2)(a)(i);

iii. Performs or assists in at least 10 hair reduction procedures; and

iv. Has the qualified health professional or qualified supervising certified laser technician certify that the laser technician has completed the training and supervision as described in subsection (B)(2)(a).

b. Ensure that the laser technician follows written procedure protocols established by a prescribing health professional; and

c. Ensure that the laser technician follows any written order, issued by a prescribing health professional, which describes the specific site of hair reduction.

3. A registrant shall maintain a record of each hair reduction procedure protocol that is approved and signed by a prescribing health professional, and ensure that each protocol is reviewed by a prescribing health professional, at least annually.

4. A registrant shall:

a. Maintain each procedure protocol onsite, and ensure that the protocol contains instructions for the patient concerning follow-up monitoring; and

b. Design each protocol to promote the exercise of professional judgment by the laser technician commensurate with the individual's education, experience, and training. The protocol need not describe the exact steps that a qualified laser technician should take with respect to a hair reduction procedure.

5. A registrant shall require that a prescribing health professional observe the performance of each laser technician during procedures at intervals that do not exceed six months. The registrant shall maintain a record of the observation for three years from the date of the observation.

6. A registrant shall verify that a health professional is qualified to perform hair reduction procedures by obtaining evidence that the health professional has received relevant training specified in R12-1-1438(A)(1) and in physics, safety, surgical techniques, pre-operative and post-operative care and can perform these procedures within the relevant scope of practice, as defined by the health professional's licensing board.

7. A registrant shall provide radiation safety training to all personnel involved with hair reduction procedures, designing each training program so that it matches an individual's involvement in hair reduction procedures. The registrant shall maintain records of the training program and make them available to the Agency for three years from the date of the program, during and after the individual's period of employment.

C. Other Cosmetic Procedures

1. If a registrant is using a medical laser or an IPL device that is a Class II surgical device, certified in accordance with the labeling~~,~~ standards in subsection (A), for other cosmetic procedures, the registrant shall.

a. Ensure that the device is only used by a health professional described in A.R.S. §§ 32-516(F)(3) and 32-3233(D)(1) or by a certified laser technician who directly supervised by a health professional as described in A.R.S. §§ 32-516(C)(2) and 32-3233(D) and (H)(2); and

b. Ensure that a prescribing health professional purchases or orders the Class II surgical device that will be used for other cosmetic procedures.

2. A registrant shall not permit an individual to use a medical laser or IPL device for other cosmetic procedures unless the individual:

a. Completes an approved laser technician didactic training program of at least 40 hours duration. To successfully complete the training program the individual shall pass a test that consists of at least 50 multiple choice questions on subjects covered with a minimum grade of 80%. The training program shall be provided by an individual who is a health professional acting within their scope of practice, or a certified laser technician with a minimum of 100 hours of hands-on experience per procedure being taught;

b. Is present in the room for at least 24 hours of hands-on training, conducted by a health professional or a certified laser technician as described in subsection (C)(2)(a); and

c. Performs or assists in at least 10 cosmetic procedures governed by subsection (C), for each type of procedure (for example: spider vein reduction, skin rejuvenation, non-ablative skin resurfacing

d. Has the qualified health professional or qualified supervising certified laser technician certify that the laser technician has completed the training and supervision as described in subsection (C)(2).

3. A registrant shall maintain a record of each protocol for a cosmetic procedure governed by subsection (C) that is approved and signed by a prescribing health professional, and ensure that each protocol is reviewed by a prescribing health professional, at least annually. The registrant shall:

a. Maintain each protocol onsite, and ensure that the protocol contains instructions for the patient concerning follow-up monitoring; and

b. Design each protocol to promote the exercise of professional judgment by the laser technician commensurate with the individual's education, experience, and training. The protocol need not describe the exact steps that a qualified laser technician should take with respect to a cosmetic procedure governed by subsection (C).

4. A registrant shall verify that a health professional is qualified to perform laser, IPL, and related procedures, by obtaining evidence that the health professional has received relevant training specified in R12-1-1438(A)(1) and in physics, safety, surgical techniques, pre-operative and post-operative care and can perform these procedures within the relevant scope of practice, as defined by the health professional's licensing board.

5. A registrant shall provide radiation safety training to all personnel involved with cosmetic procedures governed by subsection (C), designing each training program so that it matches an individual's involvement in each procedure. The registrant shall maintain records of the training program and make them available to the Agency for three years from the date of the program, during and after the individual's period of employment.

D. Persons governed by this Section shall also comply with other applicable licensing and safety laws.

E. A laser shall be secured so that the laser cannot be removed from the facility and the on/off switch is turned to the "off" position with the key removed when a certified laser technician or a health professional is not present in the room where the laser is located.

Historical Note

Adopted effective April 2, 1990 (Supp. 90-2). Repealed effective January 2, 1996 (Supp. 96-1). New Section made by final rulemaking at 11 A.A.R. 978, effective April 3, 2005 (05-1). **Amended effective Aug. 10, 2010 (Not Codified as of August 31, 2010).**

R12-1-1438.01 Certification and Revocation of Laser Technician Certificate

A. An applicant for a laser technician certificate shall submit a completed application and certification that the applicant has received the training specified in A.R.S. § 32-516(A) or A.R.S. § 32-3233(E).

B. The applicant shall pay a nonrefundable fee of $30.00. A duplicate certificate may be requested at the time of initial application or renewal at a fee of $10.00 per certificate. To obtain a duplicate certificate at other times a laser technician shall pay $20.00 per certificate.

C. Initial certificates are issued for 12 months and expire on the last day of the month. A renewal application shall be accompanied by a renewal fee of $30.00 each year in addition to $10.00 per duplicate certificate requested.

D. Under A.R.S. § 32-3233(I) and (J), the Agency may take appropriate disciplinary action, including revocation of the certificate of a certified laser technician. The Agency may discipline a certified laser technician who has had a relevant professional license suspended or revoked, or been otherwise disciplined by a health professional board or the Board of Cosmetology. The Agency may also discipline the certified laser technician for falsifying documentation related to training, prescriptions, or other required documentation. As provided in Article 12 of this Chapter, the Agency may assess civil penalties, suspend, revoke, deny, or put on probation a certified laser technician.

E. A laser technician that has been using laser and IPL devices prior to November 24, 2009 may continue to do so if the technician applies for and receives a certificate from the Agency before October 1, 2010.

F. Certification may be issued for one or more of the following procedures:

1. Hair Reduction,
2. Skin Rejuvenation,
3. Non-Ablative Skin Resurfacing,
4. Spider Vein Reduction,
5. Skin Tightening,
6. Wrinkle Reduction,
7. Laser Peel,
8. Telangiectasia Reduction,
9. Aquired Adult Hemangioma Reduction,
10. Facial Erythema Reduction,
11. Solar Lentigo Reduction (Age Spots),
12. Ephelis Reduction (Freckles),
13. Acne Scar Reduction,
14. Photo Facial, or
15. Additional procedures as approved by the Agency after consultation with other health professional boards as defined in A.R.S. § 32-516 (F)(3) or A.R.S. §32-3233(D)(1) .

G. For any application relating to the certification of laser technicians, as described in A.R.S. § 41-1072, there is an administrative completeness review time-frame of 30 days and a substantive review time-frame of 30 days with an overall time-frame of 60 days.

H. Certified laser technicians shall display a valid original certificate as issued by the Agency in a location that is viewable by the public.

Historical Note

Amended effective Aug. 10, 2010 (Not Codified as of August 31, 2010).

R12-1-1439. Laser and IPL Laser Technician and Laser Safety Training Programs

A. A person seeking to initiate a medical laser or IPL laser technician training program shall submit an application to the Agency for certification that contains a description of the training program. In addition, the person shall submit a syllabus and a test that consists of at least 50 multiple choice questions on subjects covered. In the program materials, the person shall address the subjects in R12-1-1438 through R12-1-1439, and Appendix C.

B. The Agency shall review the application and other documents required by subsections (A) and (E) in a timely manner, using an administrative completeness review time-frame of 40 days and a substantive review time-frame of 20 days with an overall time frame of 60 days.

C. The Agency shall maintain a list of certified laser or IPL training programs.

D. Applicants for approval as a certified laser or IPL training program shall pay a nonrefundable $100.00 fee.

E. Initial certification shall be issued for 12 months and shall expire on the last day of the month. A renewal application shall be accompanied by a renewal fee of $100.00 each year.

F. A person seeking to initiate a medical laser or IPL laser technician safety training program shall submit an application to the Agency for certification that contains a description of the training program. In addition, the person shall submit a syllabus and a test that consists of at least 50 multiple choice questions on subjects covered. In the program materials, the person shall address the subjects in R12-1-1421 through R12-1-1444, Appendix C, and Appendix D, with emphasis on personal and public safety. The program shall also contain the training required by A.R.S. § 32-3233(E) or clearly state the portions of the training that are not provided or met if didactic certification is to take place in another program. The applicant shall conduct training in accordance with the program submitted to the Agency and certified by the Agency.

Historical Note

Adopted effective April 2, 1990 (Supp. 90-2). Amended effective January 2, 1996 (Supp. 96-1). Section repealed; new Section made by final rulemaking at 11 A.A.R. 978, effective April 3, 2005 (Supp. 05-1). **Amended effective Aug. 10, 2010 (Not Codified as of August 31, 2010).**

R12-1-1440. Medical Lasers

A. A registrant shall ensure that a Class 3 and Class 4 laser product used in the practice of medicine has a means for measuring the level of laser radiation with an error in measurement of no greater than +20%, when calibrated in accordance with the laser product manufacturer's calibration procedure.

B. A registrant shall calibrate a laser used in the practice of medicine according to the manufacturer's specified calibration procedure, at intervals that do not exceed those specified by the manufacturer.

C. In a medical facility where several medical disciplines or a number of different practitioners use Class 3b and Class 4 lasers, a registrant shall form a Laser Safety Committee to govern laser activity, establish use criteria, and approve operating procedures, as follows:

1. With regard to membership of the committee the registrant shall include at least one representative of the Nursing staff, the LSO, one management representative, and one representative of each medical discipline that uses the lasers;
2. The committee shall review actions by the LSO related to hazard evaluation and the monitoring and control of laser hazards; and
3. The committee shall approve or deny requests by potential operators and ancillary personnel to operate or assist in the operation of a laser under the direction of a licensed practitioner.

D. A registrant shall use Class 3b and Class 4 Lasers that have a guard mechanism on the switch to control patient exposure and prevent inadvertent exposure.

E. A registrant shall establish a written laser safety training program that provides a thorough understanding of established procedures for each type of laser in use and the medical procedures associated with use of the laser. The registrant shall make program documentation available for Agency review and, at minimum, address all of the following in the documentation:

1. Regulatory requirements and the laser classification system;
2. Fundamentals of laser operation and the significance of specular and diffuse reflections;
3. Biological effects of laser radiation on the eye and skin;
4. Non-beam hazards (for example: electrical, chemical, and reaction by-product hazards) and ionizing radiation hazards (for example: x-rays from power sources and target interactions, if applicable) of lasers; and
5. Responsibilities of management and employees regarding control measures.

Historical Note

Adopted effective April 2, 1990 (Supp. 90-2). Amended effective January 2, 1996 (Supp. 96-1). Section repealed; new Section made by final rulemaking at 11 A.A.R. 61, effective February 5, 2005 (Supp. 04-4).

R12-1-1441. Laser Light Shows and Demonstrations

A. Before a conducting laser light show or laser demonstration, a registrant shall provide documentation to the Agency that a variance from 21 CFR 1040.10 has been obtained form the FDA.

B. A registrant shall notify the Agency in writing, at least three working days in before a proposed laser light show or demonstration, and include all of the following information:
   1. The location, time, and date of the light show or demonstration;
   2. Sketches showing the locations of each laser, operator, performer, laser beam path, viewing screen, wall, mirror ball, or any other reflective or diffuse surface that could be hit by or reflect the laser beam;
   3. Scanning beam patterns, scan velocity, and frequency in occupied areas; and
   4. Physical surveys and calculations made to comply with this Article.

C. A registrant shall supply any additional information required by the Agency for the safety evaluation of the proposed activity.

D. Before an outdoor laser light show, a registrant shall notify the Federal Aviation Administration of the proposed show.

E. If a light show or demonstration involves laser radiation emissions outside the spectral range of 400 to 700 nanometers, a registrant shall prevent the emissions from exceeding the applicable Class 1 accessible emission limit.

F. If it is likely that an audience member or any operator, performer, or employee will view laser or collateral radiation, a registrant shall prevent the radiation from exceeding the applicable Class 1 accessible emission limit.

G. Even if it is unlikely that an individual, including any operator, performer, or employee in the vicinity of a laser light show or demonstration will view or be exposed to laser or collateral radiation, a registrant shall prevent the radiation from exceeding the applicable Class 2 accessible emission limit.

H. A registrant shall identify any area where levels of laser radiation exceed the applicable Class 2 accessible emission limit by posting warning signs and using barriers or guards to prevent entry.

I. If a registrant uses a scanning device, the registrant shall not use a device which, as a result of scan failure or any other failure, can change its angular velocity or amplitude, permitting audience exposure to laser radiation that exceeds the applicable Class 1 accessible emission limit.

J. If a mirror ball is used with a scanning laser, a registrant shall meet the requirements of subsections (F) and (G) when the mirror ball is stationary or during any failure mode that results in a change in the rotational speed of the mirror ball.

K. A registrant shall ensure that an operator is at all times directly and personally supervising a laser light show or demonstration, except in cases where the maximum laser power output level is less than 5 milliwatts (all spectral lines) and the laser beam path is located at all times at least 6 meters above any surface upon which an individual in the audience is permitted to stand, and at any point, more than 2.5 meters in lateral separation from any position where an individual in the audience is permitted during the performance.

L. A registrant shall prevent laser radiation levels from exceeding the applicable Class 2 accessible emission limit at any point less than three meters above any surface upon which an individual in the audience is permitted to stand and 2.5 meters in lateral separation from any position where an individual in the audience is permitted, unless physical barriers are present that prevent human access to the radiation.

M. A registrant shall limit the maximum power output of any laser to a level sufficient to produce the desired effect.

N. If a registrant is required to limit output power to a level less than the available power to meet the requirements of this Article, the registrant shall adjust, measure, and record the laser output power before the laser light show or demonstration.

O. A registrant shall functionally test and evaluate all safety devices and procedures necessary to comply with this Article after setup, and before a laser light show or demonstration.

P. A registrant shall secure a laser system, when not in use, against unauthorized operation or tampering

Q. A registrant shall perform laser alignment procedures with the laser output power reduced to the lowest practicable level, and ensure that any operator, performer, or other employee wears protective eyewear as necessary to prevent exposure to radiation levels that exceed the applicable MPE. The registrant shall only allow individuals who are performing the alignment be present during alignment procedures.

R. A registrant shall not conduct a laser light show or demonstration unless the Agency has specifically exempted the show or demonstration from the requirements of 21 CFR 1040.10, April 1, 2004, which is incorporated by reference, published by the Office of Federal Register National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. This incorporation by reference contains no future editions or amendments.

Historical Note

Adopted effective April 2, 1990 (Supp. 90-2). Amended effective January 2, 1996 (Supp. 96-1). Section repealed; new Section made by final rulemaking at 11 A.A.R. 61, effective February 5, 2005 (Supp. 04-4).

R12-1-1442. Measurements and Calculations to Determine MPE Limits for Lasers

A registrant shall take measurements to determine MPE values in a manner consistent with the procedures contained in ANSI Z136.1-2000, American National Standard for Safe Use of Lasers, 2000 edition, which is incorporated by reference, published by the Laser Institute of America, 13501 Ingenuity Drive, Suite 128, Orlando, FL 32826, and on file with the Agency. This incorporation by reference contains no future editions or amendments.

Historical Note

Adopted effective April 2, 1990 (Supp. 90-2). Repealed effective January 2, 1996 (Supp. 96-1). New Section made by final rulemaking at 11 A.A.R. 61, effective February 5, 2005 (Supp. 04-4).

R12-1-1443. Laser Compliance Measurement Instruments

A registrant shall ensure that the radiation output measurement is performed with an instrument that is calibrated and designed for use with the laser that is being evaluated for compliance. The registrant shall specify the date of calibration, accuracy of calibration, wavelength range, and power or energy of calibration on a legible, clearly visible label attached to the instrument.

Historical Note

Adopted effective April 2, 1990 (Supp. 90-2). Section heading amended effective January 2, 1996 (Supp. 96-1). Amended by final rulemaking at 11 A.A.R. 61, effective February 5, 2005 (Supp. 04-4).

R12-1-1444. Laser Classification Measurements

A. A registrant shall measure accessible emission for classification:

1. Under the operational conditions and procedures that maximize accessible emission levels, including start-up, stabilized operation, and shutdown of the laser or laser facility;
2. With all controls and adjustments listed in the operating and service instructions adjusted for the maximum accessible emission level of laser radiation that is not expected to be detrimental to the functional integrity of the laser or enclosure;
3. At points in space to which human access is possible for a given laser configuration. If operations include the defeat of safety interlocks or removal of portions of the protective housing or enclosure, the registrant shall measure accessible emission at points accessible in that configuration;
4. With the measuring instrument detector positioned so that the maximum possible radiation is measured by the instrument; and
5. With the laser coupled to the type of laser energy source specified as compatible by the laser manufacturer and producing the maximum emission of accessible laser radiation.

B. A registrant shall perform measurements of accessible emission levels, used to classify laser and collateral radiation in accordance with 21 CFR 1040.10, April 1, 2004, which is incorporated by reference, published by the Office of Federal Register National Archives and Records Administration, Washington, D.C. 20408, and on file with the Agency. This incorporation by reference contains no future editions or amendments.

Historical Note

Adopted effective April 2, 1990 (Supp. 90-2). Section heading amended effective January 2, 1996 (Supp. 96-1). Amended by final rulemaking at 11 A.A.R. 61, effective February 5, 2005 (Supp. 04-4).

Appendix A. Radio Frequency Devices (Include, but are not limited to, the following)

Dielectric heaters and sealers
Medical diathermy units
Radar
R.F. activated alarm systems
Sputter devices
R.F. activated lasers
Edge gluers
Industrial microwave ovens and dryers
Asher-etcher equipment
R.F. welding equipment
Medical surgical coagulators

Historical Note

Adopted effective April 2, 1990 (Supp. 90-2). Amended by final rulemaking at 11 A.A.R. 61, effective February 5, 2005 (Supp. 04-4).

Appendix B. Application Information

The Agency shall issue a registration if an applicant provides the following information and fee as required in R12-1-1401(D). The Agency shall provide an application form to the applicant with a guide and upon request, assist the applicant to ensure that correct information is provided on the application form.

Name and mailing address of applicant
Person responsible for radiation safety program
Type of facility
Legal structure and ownership
Radiation source information
Shielding information
Equipment operator instructions and restrictions
Classification of professional in charge
Type of request: amendment, new, or renewal

Protection survey results, if applicable
Radiation Safety Officer name, if applicable
Laser class and type, if applicable
Information required by Article 14 for the specific source
Use location
Telephone number
Facility subtype
Signature of certifying agent
Equipment identifiers
Scale drawing
Physicist name and training, if applicable
Contact person
Applicable fee listed in Article 13 schedule

Historical Note

Adopted effective April 2, 1990 (Supp. 90-2). Repealed effective January 2, 1996 (Supp. 96-1). Appendix repealed by final rulemaking at 9 A.A.R. 4302, effective November 14, 2003 (Supp. 03-3). New appendix made by final rulemaking at 11 A.A.R. 61, effective February 5, 2005 (Supp. 04-4).

Appendix C. Hair Removal and Other Cosmetic Laser or IPL Operator Training Program

1. General Considerations. An applicant shall ensure that:
    a. The training program is specific to the medical laser or IPL device in use and the clinical procedures to be performed;
    b. Program content is consistent with facility policy and procedure and applicable federal and state law; and
    c. The training program addresses hazards associated with laser or IPL device use.
2. Technical Considerations. The applicant's training program shall cover all of the following technical subjects:
    a. Laser and IPL device descriptions
    b. Definitions
    c. Laser and IPL device radiation fundamentals
    d. Laser mediums, types of lasers, and other light-emitting devices - solid, liquid, gas, and IPL devices
    e. Biological effects of laser or IPL device light
    f. Damage mechanisms
        i. Eye hazard
        ii. Skin hazard (includes information regarding skin type and skin anatomy)
        iii. Absorption and wavelength effects
        iv. Thermal effects
    g. Photo chemistry
    h. Criteria for setting the Maximum Permissible Exposure (MPE) for eye and skin associated hazards
    i. Explosive, electrical, and chemical hazards
    j. Photosensitive medications
    k. Fire, ionizing radiation, cryogenic hazards, and other hazards, as applicable
3. Medical Considerations. The applicant's training program shall cover all of the following medical subjects:
    a. Local anesthesia techniques, including ice, EMLA® cream, and other applicable topical treatments
    b. Typical laser and IPL device settings for hair removal and cosmetic procedures
    c. Expected patient response to treatment
    d. Potential adverse reactions to treatment
    e. Anatomy and physiology of skin areas to be treated
    f. Indications and contraindications for use of pigment and vascular-specific lasers for cutaneous procedures
4. General Laser or IPL device safety. The applicant's training program shall cover the following general safety subjects:
    a. Laser and IPL device classifications
    b. Control measures (includes information regarding protective equipment)
    c. Manager and operator responsibilities
    d. Medical surveillance practices
    e. Federal and state legal requirements
    f. Related safety issues
        i. Controlled access
        ii. Plume management
        iii. Equipment testing, aligning, and troubleshooting

Historical Note

New appendix made by final rulemaking at 11 A.A.R. 978, effective April 3, 2005 (Supp. 05-1).

Appendix D. Laser Operator and Laser Safety Officer Training

1. Operators and personnel that work around lasers:
    a. Fundamentals of laser operation (for example: physical principles, construction, and other basic information)
    b. Bioeffects of laser radiation on the eye and skin
    c. Significance of specular and diffuse reflections
    d. Non-beam hazards of lasers (for example: electrical, chemical, and reaction byproducts)
    e. Ionizing radiation hazards (includes information regarding x-rays from power sources and target interactions, if applicable)
    f. Laser and laser system classifications
    g. Control measures
    h. Responsibilities of managers and operators
    i. Medical surveillance practices (if applicable)
    j. CPR for personnel servicing lasers with exposed high voltages, the capability of producing potentially lethal electrical currents, or both.
2. The LSO or other individual responsible for the safety program, evaluation of hazards, and implementation of control measures, or any others, if directed by management to obtain a thorough knowledge of laser safety:
    a. The subjects covered in subsection (1)
    b. Laser terminology
    c. Laser types, wavelengths, pulse shapes, modes, power and energy
    d. Basic radiometric units and measurement devices
    e. MPE levels for eye and skin under all conditions
    f. Laser hazard evaluations, range equations, and other calculations
3. Technical Considerations
    a. Laser and IPL device descriptions
    b. Definitions
    c. Laser and IPL device radiation fundamentals
    d. Laser mediums, types of lasers, and other light-emitting devices (includes information regarding diodes and solid, liquid, gas, and IPL devices)
    e. Biological effects of laser or IPL device light
    f. Damage mechanisms
        i. Eye hazard
        ii. Skin hazard (includes information regarding skin type and skin anatomy)
        iii. Absorption and wavelength effects
        iv. Thermal effects
    g. Photo chemistry
    h. Photosensitive medications
    i. Criteria for setting the Maximum Permissible Exposure (MPE) levels for eye and skin associated hazards
    j. Explosive, electrical, and chemical hazards
    k. Fire, ionizing radiation, cryogenic hazards, and other hazards as applicable

Historical Note

New appendix made by final rulemaking at 11 A.A.R. 978, effective April 3, 2005 (Supp. 05-1).